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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/598,890	06/22/2000	Manfred Berndt	4481-022	8565

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EXAMINER

GORDON, BRIAN R

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 10/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/598,890

Applicant(s)

BERNDT, MANFRED

Examiner

Brian R. Gordon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8-13-03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-27, 29-42, 44--55 is/are rejected.
- 7) ☒ Claim(s) 28 and 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 11 June 2003 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 24.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 13, 2003 has been entered.

Response to Amendment

2. Applicant has amended claim 17 to remove a recitation to the microchip. In view of the amendment it appears as if applicant only intends to claim "a supply element". For the purpose of examination, the new claim is now being interpreted as a supply element comprising at least one substance-containing first supplier, said at least one first supplier having a seal arranged to be opened. The remaining portion of the claim that is directed to the microchip is directed to intended use of the supply element for the microchip is not an element of the invention.

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

As such, the claim is broadly interpreted as a sealed, substance-container that can be opened.

Drawings

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1. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on June 11, 2003 have been approved.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Applicant fails to specifically refer to the elements the invention as the terminology (third supplier and fourth supplier) used in the claims; therefore it is unclear exactly which elements of the invention are considered to be the third supplier and fourth supplier. For the purpose of clarity for the examiner, it is hereby requested that applicant explain what elements applicant considers as first, second, third, and fourth suppliers.

The specification does not provide support for claim 25 that recites the third supplier comprises at least one substance sample and at least one substance reagent. As understood by the examiner the samples and reagents are contained in separate suppliers and are mixed after being introduced into the microchip.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 47-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

While the preamble of the claim 47 recites that the invention is a combination of a supply element and a microchip, the supply element and the microchip. It is suggested the claim be amended to recite: comprising: a microchip; a supply element.

As to claims 48-50, the preamble should read "the laboratory microchip".

It is also unclear if the limitations of claim 49 are directed to the supply element or the microchip. For example in claim 49, are the assemblies a part of the supply element or the microchip? It appears as if the assemblies are separate elements from the combination of the microchip and the supply element.

It is unclear exactly which elements of the invention are considered to be the third supplier and fourth supplier.

As to claim 29, the word "the" should be inserted before supply equipment.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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6. Claims 17-25, 27, and 30-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Lebl et al. US 6,045,755.

Lebl et al. discloses reaction vessel (supply element with substance) embodiments, which are capable of containing reaction mixtures for combinatorial chemistry. The reaction vessels can include, alternatively, stackable, ball-sealed reaction vessels, microtitre-like reaction vessel arrays, arrays of independent reaction vessels, valve-sealed reaction vessels, septum-sealed (allows substance to be removed) reaction vessels, and syringe reaction vessels. Preferable reaction vessels are inexpensive commercially available vessels, microtitre plates, and so forth, capable of resisting the solvents and reaction conditions used in synthesis protocols. Reaction vessel arrays are sealed with various sealing means.

Alternatively, this invention includes reaction vessel arrays which are arrays of syringes, each syringe including a microporous frit for retaining a solid-phase synthesis support while permitting free passage of fluids. Such syringe arrays can be constructed either from a block of solvent resistant plastic having an array of cylindrical cavities forming the syringe bodies or from independent, commercially-available syringes held in an array by a support means. However constructed, fluid manipulation and distribution can be provided by a network of passageways, each such passageway connecting to one syringe body and externally terminated either by a needle or by a septum.

In the case of septum termination, for fluid dispensing to the individual syringe bodies, the septums can be penetrated by needles containing required fluids.

FIG. 11A illustrates a reaction vessel sealed with a single septum. Here reaction vessel 300 is preferably of approximately 4 ml capacity, and is made of glass or a solvent resistant plastic. Septum 301 is of a solvent resistant rubber material capable of being punctured by, e.g., a 14 gauge needle and then resealing itself. Septum 301 is preferably made of a Teflon. coated rubber or of an elastomer of Kalrez type. Collar 302 seals septum 301 to reaction vessel 300, and is of, for example, aluminum or plastic. This invention is adaptable to commercially available, inexpensive septum-sealed reaction vessels, such as the reaction vessels obtained from such suppliers as Phase Separations (Franklin, Mass.) or ColePalmer (Niles, Ill.). Septum-sealed reaction vessels are retained for processing in arrays of standardized structure by holding hold blocks of standardized sizes, as in other reaction vessel embodiments of this invention. One exemplary such holding block is holding block 151 of FIG. 6A.

The invention also includes arrays of syringe-like reaction vessels. Syringe-like reaction vessels include porous frits in their bases for retaining solid-phase substrates while permitting relatively free movement of fluids. A preferred frit is made of polypropylene with a 5-30 micron pore size, a porosity of 50%, and capable of retaining solid-phase microbeads with a diameter >30 microns. Fluid handling for syringe arrays made according to either embodiment can, alternatively, be based on aspiration through needles from individual fluid storage vessels or on aspiration through a fluid distribution block from common fluid storage vessels. Exemplary syringe-like reaction vessel array layouts include a linear array of 8 syringes, an array of 24 syringes in a 4X6 rectangular arrangement, and an array of 96 syringes in a 8X12 rectangular arrangement.

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7. Claims 17-21, 23-27, 29-42, and 44-55 rejected under 35 U.S.C. 102(e) as being anticipated by Chow 6,071,478.

Chow discloses an analytical or preparatory system comprised as a base unit, an adapter, and a substrate. The adapter is attached to an attachment region on the base unit, and the substrate is attached to an attachment region on the adapter. The adapter permits the base unit to be interfaced with a wide variety of different substrates to perform chemical and biological analytical analyses and preparatory procedures.

The analytical systems may provide for a variety of manipulations of the sample in addition to chemical and biological reactions, such as mixing, dispensing, valving, separation, heating, cooling, detection, and the like.

The sample substrate is usually a microfluidic substrate but could be any other sample substrate capable of receiving test specimen(s) or starting material(s) for processing or providing a detectable signal, where the base unit manages sample flow, reagent flow, and other aspects of the analytical and/or preparatory technique(s).

The base unit, adapter and sample substrate will be configured so that they may be physically joined to each other to form the analytical system. For example, the attachment region in the base unit may be a cavity, well, slot, or other receptacle which receives the adapter, where the dimensions of the receptacle are selected to mate with the adapter. Similarly, the attachment region on the adapter may comprise a receptacle, well, slot, or other space intended to receive the sample substrate and position the substrate properly relative to the adapter and or base unit. The sample substrate will preferably employ mesoscale fluid channels and reservoirs, i.e. where the channels

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have at least one dimension in the range from 0.1 μm to 500 μm usually from 1 μm to 100 μm .

When the system of the present invention is controlled via digital circuitry, i.e. using a separate conventional computer interfaced with the base unit or using digital control circuitry incorporated within the base unit, it will usually be desirable to provide at least a portion of the operating instructions associated with any particular adapter and/or any particular sample substrate and assay format in a computer-readable form, i.e. on a conventional computer storage medium, such as a floppy disk, a compact disk (CD ROM), tape, flash memory, or the like. The medium will store computer readable code setting forth the desired instructions, where the instructions will enable the computer (which may be a separate or integral computer) to interface with the base unit and to control an assay performed by the base unit upon the sample present on a sample substrate held by an adapter received on the base unit. The present invention thus comprises the computer program itself in the form of a tangible medium, e.g. disk, CD, tape, memory, etc., which may be used in combination with the system of the present invention. The present invention further comprises systems which include an adapter as set forth above in combination with the tangible medium storing the computer instructions described above. The present invention still further comprises systems which are combinations of one or more sample substrates as generally set forth above, together with a tangible medium setting forth computer readable code comprising instructions as set forth above.

Electrical connections, both for power and signal transfer, will generally comprise conventional connectors in the form of electrodes, pins, plugs, zero insertion force (ZIF) connectors, and the like. Such electrical connections will usually require mating connectors in two of the interface arrays which are brought together when the system is put together. The electrical connectors will often be present on a surface or edge of the interface array so that corresponding components will be engaged against each other when the adapter is mounted in the base unit or the substrate is mounted on the adapter. Similarly, surface or edge electrodes in the adapter-sample substrate interface array may be provided to mate with corresponding surface or edge electrodes on the sample substrate. The electrodes on the sample substrate may then be connected internally in the substrate to the desired reservoirs or fluid flow channels in order to effect electrokinetic flow control, as described in the previously incorporated patents and patent applications. In other cases, however, it will be desirable to provide interface components in the adapter-sample substrate interface array which directly contact the fluid to be electrokinetically controlled. For example, probes or pins may be provided on the adapter which will penetrate into open wells or through septums on the sample substrate in order to permit direct contact and application of electrical potential.

The flow biasing connectors may be probes or pins on the adapter which are positioned to directly engage fluids present on or in the sample substrate. For example, an array of pins may be provided on a hinged lid or cover on the adapter plate so that the sample substrate may be positioned on the adapter and the lid cover thereafter closed in order to penetrate the pins into open sample wells on the substrate. The

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sample wells, of course, need not be open and could be covered with any penetratable membrane or septum which is pierced by the pins when the cover is closed. Other flow biasing connectors include acoustic energy sources (piezoelectric transducers) positioned within the adapter-sample substrate interface array so that they engage the sample substrate at positions intended to induce fluid flow through the flow channels.

Allowable Subject Matter

8. Claims 28 and 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach nor fairly suggest a supply element that comprises an attachment arrangement that comprise a bayonet lock.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hubbard et al., Chow (,023), Cherukuri et al., Pfoest et al., McEntee et al., Caramanica, Jr., Tajima, Gamble, Finney et al., Paul et al., Schembri, Skinner et al., Dorn et al., and Parrent, Jr. et al. disclose fluid containers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is (703) 305-0399. The examiner can normally be reached on M-F, with 2nd and 4th F off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for

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the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

brg
October 20, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700